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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,129

02/04/2004

Shaun Hanson

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37902

7590

12/23/2008

WRIGHT MEDICAL TECHNOLOGY, INC.
LEGAL DEPARTMENT
5677 AIRLINE ROAD
ARLINGTON, TN 38002-9501

EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/772,129	Applicant(s) HANSON ET AL.	
	Examiner DAVID COMSTOCK	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapandji (FR 2 660 856 A1; cited by Applicant).

Kapandji discloses an implant 1 comprising a stem 20 and a head 4 (see Fig. 2). Holes 26 pass through positions near both ends of the stem and are capable of accepting suture. The head includes a 200 degree arc. Component 30 can be considered a portion of the platform or an extension, and includes holes 27 through which suture could be passed. Kapandji discloses the claimed invention except for explicitly disclosing that the head could be provided as separate component from the stem. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the device of Kapandji with a head as a separate component from the stem, e.g., to facilitate manufacturing or to facilitate a minimally invasive procedure, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kapandji (FR 2 660 856 A1; cited by Applicant), as modified, and further in view of Wack et al. (6,027,534).

Kapandji, as modified, discloses the claimed invention except for the bone ingrowth coating. Wack et al. discloses a prosthetic implant 20 and teaches that a bone ingrowth promoting coating can be provided on the device, not only on the shaft thereof, but also on the backside of the main body, e.g. 15, thereof, in order to allow for bone ingrowth, which provides for more secure fixation (see, e.g., Fig. 1 and col. 3, line 65 - col. 4, line 18, esp. col. 4, lines 15-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant of Kapandji with a bone ingrowth promoting coating, in view of Wack et al., in order to allow for bone ingrowth and provide more secure fixation of the implant. It is noted that the backside of the head of the device of Kapandji is not an articulation surface and would have been suggested by the disclosure of Wack et al. Even if it had not been disclosed, it would have been obvious to have put the bone ingrowth promoting coating on the back of the head, e.g. to improve fixation of the device, since it has been held that relocation of the features of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claims 1-9 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooney, III et al. (6,302,915 B1; cited by Applicant) in view of Stubstad (3,745,590; cited by Applicant).

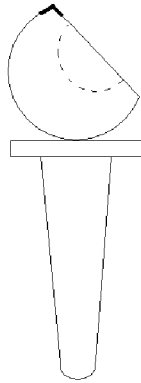
Cooney, III et al. clearly discloses the claimed invention except for the use of suture holes in portions of the device other than the head and except for the head having a through-bore. It is specifically noted that the head is a separate component from the stem (see, e.g., Fig. 2, 3A and 3B). Stubstad discloses a similar device 10 and teaches attaching a ligature or suture 22 through both the head 11 and the stem 16/platform 19 structure in order to provide a continuity of strength through the prosthesis and resist dislocation of the joint to be corrected while still providing unrestricted natural motion (see, e.g. Fig. 2; col. 1, lines 5-11; and col. 2, lines 44-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant device of Cooney, III et al. with holes in portions other than the head, such as the stem and platform, in view of Stubstad, in order to provide a continuity of strength through the prosthesis and resist dislocation of the joint to be corrected while still providing unrestricted natural motion. It would have been further obvious to have selected a bore depth in the head within a range resulting in a through bore, e.g. to make the device lighter and/or to provide other anchoring options, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. With regard to the particular locations of the various holes etc. it also would have been obvious to have positioned these at any of various locations on the device, e.g. to address the varying anatomical and physical requirements of different patients and conditions, since it has been held that mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusions of obviousness are based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, the motivations are derived from the references themselves and from the knowledge generally available to a person of ordinary skill in the art. The motivations are set forth in the rejection.

Applicant's discussion of the cavity in the Kapandji reference still does not change the fact that the reference shows an enlarged portion on the end thereof, i.e. a head. While Examiner agrees that the inner portion of the head has a cavity, this does not in any way change the fact that the outer surface or extent thereof defines a head. In addition, the vertex and adjacent surfaces where the convex portion meets the planar face surrounding the cavity (see, e.g. Fig. 2 and Example below) a "triangulated configuration." It is further noted, regarding the amended claims, that the triangulated configuration never ceases to exist regardless of whether or not it is prominent from a certain point of view.



Example

Moreover, the head can be considered to be “configured” for mating with a sigmoid notch, at least because the term “mating” requires only that they be capable of least contacting each other. In addition, regarding the intended use of passing sutures through the holes, the device of Kapandji has holes through which suture is capable of being passed.

Regarding the rejection under 35 USC 103, it is noted that Cooney teaches holes as an attachment means; Stubstad is cited as teaching the attachment of the suture at both the head and the stem/platform structure. The way that Stubstad attaches the suture 22 to the device is not material, since it is not being cited for that proposition. It is being cited for the concept of attaching the suture 22 at the noted locations. In addition, in the same way that the Kapandji reference can be seen as showing a

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"triangulated configuration," so too can the Cooney reference, also at the vertex of the planar portion and the convex portion (as exemplified above in the diagram; *cf.* Cooney Fig. 3A, e.g., the upper left portion). Regarding the motivation to combine and/or modify the references as set forth in the rejection, it is noted that the reason for modifying the combination of references was already set forth in the rejection. Regarding the depth of the bore, beyond the reasons set forth in the rejection, another reason to change it would be to discover an "optimum or workable range" of the same for a given patient or surgical requirement. In the context of a surgical procedure the workable range, for example, can be controlled by patient anatomy or condition or other surgical requirements requiring a modified installation. In any event, it has been held to be obvious to make such modifications and doing so would hardly require a person of ordinary skill in the art to have to consult the Applicant's disclosure to understand how or why to change the dimensions. The reason for positioning the holes in different locations was also given in the rejection: relocation. Again, in the context of a surgical procedure, it would have been obvious to a person of ordinary skill in the art to have positioned the holes in the locations as noted in the claims and the rejection, as this, too, has been held to be obvious, and doing so can accommodate, for example varying patient anatomy, condition or other surgical requirements necessitating a modified installation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/
Examiner, Art Unit 3733
/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733